K062200

510(k) Summary of Safety and Effectiveness

FEB 13 2007

Applicant Name and Address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, New Jersey 07417
Contact Person:	Peggy Hansen, RAC Sr. Director, Clinical, Regulatory, and QA Tel: (201) 405-1477 Fax: (201) 405-1355
Date of Summary:	July 28, 2006
Device Common Name:	Bone Grafting Material Bone Void Filler
Device Trade Name:	Collagen Matrix Anorganic Bone Mineral Bone Graft Materials
Device Classification Name:	Filler, Bone Void, Calcium Compound
Regulation Number:	888.3045
Device Class:	Class II
Product Code:	MQV
Predicate Device(s):	ORTHOSS™ Resorbable Bone Void Filler, K014289 VITOSS® Scaffold Synthetic Cancellous Bone Void Filler, K032409 OsteoGuide® Anorganic Bone Mineral Products, K043034

Description of the Device

Collagen Matrix Anorganic Bone Mineral Bone Graft Materials are natural, porous bone mineral matrices with and without collagen. The anorganic bone mineral is produced by removal of all organic components from bovine bone. Due to its natural structure, the anorganic bone mineral component of the products is physically and chemically comparable to the mineralized matrix of human bone. The composition of the Anorganic Bone Mineral meets the requirements of ASTM F1581-99 *Standard Specification for Composition of Anorganic bone for Surgical Implants*. Anorganic Bone Mineral Collagen and Anorganic Bone Mineral Blocks are product extensions that include highly purified fibrillar type I collagen mixed in with the anorganic bone mineral. The product is supplied in granules or blocks, and it is sterile, non-pyrogenic, and for single use only.

Intended Use

Collagen Matrix Anorganic Bone Mineral Bone Graft Materials are intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Summary/Comparison of Technical Characteristics

Collagen Matrix Anorganic Bone Mineral Bone Graft Materials and their predicates have the same technological characteristics. In particular, Collagen Matrix Anorganic Bone Mineral Bone Graft Materials and their predicates are the same with respect to intended use, design, materials, material characterization, form, and sizes.

Safety

Collagen Matrix Anorganic Bone Mineral Bone Graft Materials have been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The characteristics of the Collagen Matrix Anorganic Bone Mineral Bone Graft Materials meet the design requirements for an effective bone grafting material. An animal study was performed to verify substantial equivalence and effectiveness of the product.

Conclusion

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, and animal study, show that Collagen Matrix Anorganic Bone Mineral Bone Graft Materials are safe and substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2007

Collagen Matrix, Inc.
c/o Ms. Peggy Hansen, RAC
Sr. Director, Clinical, Regulatory, and Quality Assurance
509 Commerce St.
Franklin Lakes, NJ 07417

Re: K062200
Device Name: Collagen Matrix Anorganic Bone Mineral Bone Graft Materials
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 16, 2006
Received: November 17, 2006

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

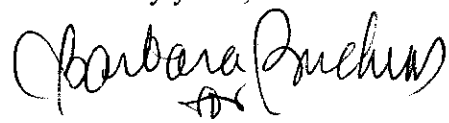
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062200

Device Name: Anorganic Bone Mineral Bone Graft Materials

Indications for Use:

Anorganic Bone Mineral Bone Graft Materials are intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062200